

REMARKS

Claims 1-41 are now pending.

Rejection Under 35 U.S.C. § 112, First Paragraph, Written Description

Applicants traverse the rejection of claims 1-41 under 35 U.S.C. § 112, first paragraph (enablement). Applicants respectfully submit that a skilled artisan would be enabled to use the claimed method to prevent inflammation. Applicants respectfully submit that the U.S. patent corresponding to WO98/34644 ('644) cited in the obviousness rejection (*i.e.*, U.S. Patent No. 6,274,614 ('614)), contains claims which are directed to “preventing the effects of inflammation.” This patent was examined by the same examiner as in the present application. Applicants respectfully submit that the test is not whether “painstaking experimentation” is necessary as alleged by the Office. Rather, MPEP § 2164.01 states that the “fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation.” Further, this section of the MPEP further states that a patent “preferably omits, what is well known in the art.” Applicants respectfully submit that experimentation related to preventing inflammation is typical in the art as illustrated by the '614 patent. Nonetheless, applicants respectfully submit that the present application contains Example 1, which shows that low dose light inhibited the increase in inflammation. Please see e.g. page 44, lines 7-8. Thus, there are adequate and detailed teachings in the present application that would enable a skilled artisan to use the claimed method to prevent inflammation. Thus, applicants respectfully submit that the enablement rejection may be properly withdrawn.

Rejection Under 35 U.S.C. § 103

Applicants traverse the rejection of claims 1-26 and 29-41 under 35 U.S.C. § 103(a) as being obvious over WO98/34644 ('644). The Office alleges that the “prior art teaches the concept of exposing a damaged tissue to a low dose photosensitizing agent or low dose light in order to reduce inflammation associated with photodynamic therapy.” The Office further alleges that the prior art “teaches that normal dose photodynamic therapy can cause inflammation.” The Office

cites page 17, lines 3-4, page 35, lines 24-29, and page 36, lines 1-15 of '644. Applicants respectfully submit that the portions of '644 cited by the Office do not describe that normal dose photodynamic therapy can cause inflammation that can be reduced or prevented by using low dose PDT. Specifically, page 17, lines 3-4 of '644 discloses that "the effects of inflammation arising from injured tissue can be reduced or prevented by low dose PDT." In addition, page 35, lines 24-29 describes "low dose PDT" as depending on the combination of the dose of photosensitizing agent and the dose of the irradiating light. Further, page 36, lines 1-15 does not describe that normal dose PDT can cause inflammation which can be treated by low-dose PDT. Specifically, page 36, lines 1-15 further define "low dose PDT" and various modes of combining photosensitizer doses, contact times, and modes of administration to achieve low dose PDT. Nowhere does this reference describe that normal dose PDT can cause inflammation which can be treated by low dose PDT.

Applicants respectfully submit that in accordance with MPEP § 2131, the identical invention must be shown as in complete detail as it is contained in the claim, and that the elements "must be arranged as required by the claim." Applicants respectfully submit that the Office has not established that '644 shows the claimed invention in "complete detail" with regard to the presence of the photosensitizer. Claims 1 and 17, for example, requires that the low dose light is absorbed by the photosensitizer used in the normal dose PDT treatment. Similarly, claim 31 defines the step of administering the photosensitizer and then performing a first dosage of radiation to occlude the neovasculature and a second lower dosage of radiation to reduce or prevent inflammation. Applicants respectfully submit that '644 does not disclose that normal dose photodynamic therapy can cause inflammation that can be remedied by low dose PDT, and certainly does not disclose or suggest the step of performing low dose PDT using the photosensitizer of the normal dose PDT. Thus, '644 does not disclose or suggest the elements nor the arrangement thereof as required by the present claims in accordance to MPEP § 2131. Applicants respectfully request the Office to clarify for the record as to why it is not necessary for '644 to disclose or suggest the claimed elements in order to establish *prima facie* obviousness.

Further, the Office has not shown that '644 shows in complete detail the claim elements regarding the defined treatment area as claimed. Claim 1 requires that the low dose PDT treatment

area overlaps with the normal dose PDT treatment area. Claim 17 requires that the low dose PDT treatment area is adjacent to the normal dose PDT treatment area. Claim 31 describes the low dose treatment area as the normal dose PDT treatment area or such treatment area and an additional area adjacent to the treatment area. Applicants respectfully request the Office to address why it is not necessary to establish such elements in complete detail to establish *prima facie* obviousness.

Moreover, the Office has not addressed the applicants' argument made in the Response filed February 21, 2006 which states that the genus of injured or pre-injured tissue does not specifically disclose the species as claimed of tissue treated with normal dose PDT (assuming for the sake of argument, the genus species relationship). As described above, inflammation arising from normal dose PDT has not been disclosed or suggested as a particular type of tissue to be treated by low dose PDT in '644. Applicants respectfully request the Office to address why it is not necessary for '644 to disclose the claimed species in order to establish *prima facie* obviousness.

Further, the Office has not established the '644 discloses or suggests the elements of new claims 33-41. Applicants respectfully request the Examiner to address why it is not necessary for '644 to disclose or suggest the elements in new claims 33-41.

Otherwise, as the Office has not established all of the elements as claimed, applicants respectfully submit that the present claims are not obvious over '644. Withdrawal of this rejection is respectfully requested.

Conclusion

U.S. Patent No. 6,274,614 and the present Example 1 provide evidence that a skilled artisan would be enabled to prevent inflammation as claimed. With respect to the obviousness rejection, the Office has not established that '644 discloses or suggests all of the claim limitations. Applicants respectfully request the Office to provide reasoning as to why claim elements need not be disclosed or suggested in order to render the claims obvious. Otherwise, applicants respectfully submit that the present claims are not obvious over '644 and request withdrawal of this rejection.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 273012011800. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: August 17, 2006

Respectfully submitted,

By _____

Carolyn A. Favorito

Registration No.: 39,183
MORRISON & FOERSTER LLP
12531 High Bluff Drive
Suite 100
San Diego, California 92130-2040
(858) 720-5195